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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,120	12/30/2003	Richard Boyd	NOR-015CP2 and 286336.154	3284

23483 7590 10/06/2006

WILMER CUTLER PICKERING HALE AND DORR LLP
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,120	BOYD ET AL.	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/13/04 & 8/25/04*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-57,61-64,66-84,87-90,92 and 94-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-57,61-64,66-84,87-90,92 and 94-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The claims pending are 38-57, 61-64, 66-84, 87-90, 92 and 94-100.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 38-57, 89 and 99-100, drawn to methods of determining susceptibility of an atrophied thymus to reactivation by means of monitoring blood/serum marker levels, classified in class 424, subclass 9.2; class 435, subclass 7.1+; and class 436, subclass 86+.

II. Claims 61, 90 and 96-97, drawn to drawn to methods of determining susceptibility of an atrophied thymus to reactivation by means of monitoring an in vitro response of blood T-cells, classified in class 424, subclass 9.2 and in class 435, subclass 6.

III. Claims 62-64, 66-84, 92, 98 and 100, drawn to drawn to methods of determining susceptibility of an atrophied thymus to reactivation by means of monitoring newly produced blood T-cells, classified in class 424, subclass 9.2 and in class 435, subclasses 6, 7.24 and 91.2.

IV. Claim 87, drawn to a method of enhancing transplantation of donor hematopoietic stem cells, classified in class 424, subclass 93.71 and in class 514/1-789.

V. Claim 88, drawn to a method of increasing virus-specific peripheral T-cell responses in a patient, classified in class 424, subclass 9.2 and in class 435, subclass 5.

VI. Claims 94-95, drawn to drawn to methods of determining susceptibility of an atrophied thymus to reactivation by means of monitoring intracellular cytokine levels in blood T-cells, classified in class 424, subclass 9.2 and in classified in class 435, subclass 7.24.

Multiple dependent claim 100 has been listed with both Groups II and III.

The inventions are independent or distinct, each from the other because:

Inventions I-III (as well as V-VI) versus IV are directed to related but distinct processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in their mode of operation and effect. Specifically the inventions of Groups I-III and V-VI are directed to determining the susceptibility of an atrophied thymus to reactivation by means of monitoring the levels of various markers, while the invention of Group IV is directed to enhancing the transplantation of donor hematopoietic stem cells. The invention of Group IV involves the steps of "depleting the T-cells" and of "transplanting donor hematopoietic stem cells" which are not conducted in any of the inventions of Groups I-III and V-VI. The inventions of Groups I-III and V-VI have one or more steps of monitoring the levels of various markers, while the invention of Group IV has no such monitoring step(s). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-III and V-VI are unrelated one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions use different methods of monitoring thymic reactivation. While there may be some overlap in the classes/subclasses to be searched, it is to be noted that a searching of the non-patent literature would be unlikely to find any reference showing or suggesting all of the recited methods of monitoring. Since those in the medical arts are motivated to publish results, based on the least possible amount of data, quickly; it is deemed that there would no motivation for one of ordinary skill to employ one of the monitoring methods in lieu of another or along with another. The methods of Groups I-III and V-VI can be practiced separately from of one another and are not obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

In the event that applicant elects one of Groups I-III or VI, the following election of species will be required:

Claims 38-42, 45-57, 89 and 99-100 of Group I; claims 61, 90 and 96-97 of Group II; claims 62-64, 66-71, 74-84, 92, 98 and 100 of Group III; and claims 94-95 of Group VI are generic to the following disclosed patentably distinct species:

Various methods of "disrupting the sex steroid-mediated signaling to the thymus", such as:

Surgical castration (e.g. claim 43),

Chemical castration (e.g. claim 44)

One or a specific combination of the numerous pharmaceuticals of claims 46-48.

The species are independent or distinct because the various methods of disrupting the sex steroid-mediated signaling to the thymus require different searches and can be practiced separately from one another. Furthermore, it is to be noted that a searching of the non-patent literature would be unlikely to find any reference showing or suggesting all of the recited methods for disrupting. Since those in the medical arts are motivated to publish results, based on the least possible amount of data, quickly; it is deemed that there would no motivation for one of ordinary skill to use one of the methods for disrupting methods in lieu of another or along with another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In the event that applicant elects Group I, the following election of species will be required:

Claims 38-57, 89 and 99-100 are generic to the following disclosed patentably distinct species:

The various markers recited in claim 57.

The species are independent or distinct because the markers recited in claim 57 represent a diverse group of analytes that would be assayed by diverse methods. While there may be some overlap in the classes/subclasses to be searched, it is to be noted that a searching of the non-patent literature would be unlikely to find any reference showing or suggesting all of the recited markers for monitoring. Since those in the medical arts are motivated to publish results, based on the least possible amount of data, quickly; it is deemed that there would no motivation for one of ordinary skill to assay for one of the markers for monitoring methods in lieu of another or along with another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

For Group I applicant is required to elect a combination of one of the distinct methods of disrupting the sex steroid-mediated signaling and one of the distinct markers for monitoring.

In the event that applicant elects Group III, the following election of species will be required:

Claims 62-63, 66-84, 92, 98 and 100 are generic to the following disclosed patentably distinct species:

The various markers recited in claims 63-64.

The species are independent or distinct because the markers recited in claim 63-64 represent a diverse group of analytes that would be assayed by diverse methods. While there may be some overlap in the classes/subclasses to be searched, it is to be noted that a searching of the non-patent literature would be unlikely to find any reference showing or suggesting all of the recited markers for monitoring. Since those in the medical arts are motivated to publish results, based on the least possible amount of data, quickly; it is deemed that there would no motivation for one of ordinary skill to assay for one of the markers for monitoring methods in lieu of another or along with another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

For Group III applicant is required to elect a combination of one of the distinct methods of disrupting the sex steroid-mediated signaling and one of the distinct markers for monitoring.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 9/25/06 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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